REMARKS -- General

By the above amendment, Applicant has rewritten the claims to more clearly define the invention patentably over the prior art.

All claims were rejected based upon 35 U.S.C. 103(a) by this Office Action.

Numbered paragraphs following refer to paragraph numbers in this Office Action.

Shigezawa and Bakke Do Not Contain Any Justification to Support Their Combination

2. Claim 1A only describes the patient flow line tubing, equivalent to claim 5 of Bakke (US 6,608,968). The present claim 1 therefore does not differ from Bakke in disclosing the tubing for the blood warmer. The tubing in each case is the same. Nor does Shigezawa disclose "A passively, still-air insulated and electrically actively warmed disposable outlet patient flow line system for in-line blood/fluid warmers comprising: a flexible tube flow line made of polyvinyl chloride or other resinous material has a central blood-carrying tube about 0.12 inch inside diameter and a wall thickness of about 0.04 inch, and is supported inside a larger tube which is co-extruded with said central tube and has an outside diameter of about 0.37 inch and a wall thickness of about 0.04 inch, said central and outer tubes being interconnected by co-extruded webs about 0.04 inch thick which appear in cross section as a planar diametrical web across the entire cross section with the exception of said central tube's lumen, wherein an annular space between said central and outer tubes is filled with heat

insulative still air," as the O.A. states. While Shigezawa correctly identifies the problem of heat loss from the patient line to cooler ambient air, his invention addresses it in a very different way. First, Shigezawa employs a single round tube as the fluid-carrying conduit, providing no passive insulation comparable to the two semi-cylindrical still air chambers of the co-extruded tubing of my invention. Thus the heat loss to be compensated for is much greater in the invention of Shigezawa, whereas in the present invention the active heating function serves only to replace the relatively small heat losses from the outer surface of the passively insulated patient i.v. tubing. Further, Shigezawa teaches an electrically heated diametric plastic web across the fluid-carrying tube as the primary means of heating blood as well as the means of compensating for convective losses to ambient air at low flow rates. Those skilled in the art will recognize the impracticability of significant heat transfer by Shigezawa's method except at very low flow rates. Previous attempts at heating through the outer walls of the patient line by immersion in heated and even stirred water have been unable to deliver high flow rates of normothermic fluid. Shigezawa's heat transfer area for convective heating of fluid is less than that of heating the outer surface of the same tubing by a factor of about 2.3.

The present invention is designed to accept pre-warmed fluid at 37-42C, not to actively warm the fluid. By just maintaining the still air in the insulating air chambers of the patient line tubing at about 37-42C, heat loss from the blood to ambient air is prevented, and fluid is delivered to the patient connection at normothermic temperature.

Rejection of Claims 1 through 7 on Bakke, Bakke, Shigezawa, and Jordan Overcome

3. Claim 1B is only a part of the totality of claim 1. Claim 1B only describes the necessary connections to the blood warmer outlet and to the patient i.v. site. Examiner here states, "The claim differs from Bakke in disclosing the method of heating." While not in claim 1B, it is true that this invention differs from Bakke (US 6,608,968) in disclosing the method of heating. The details of the method of heating comprise, in fact, the useful, novel and unobvious material of the present invention. The present invention provides a clean, dry heat, simple, low cost, disposable solution to a long-recognized problem. In utilizing the resistance heating wire itself as the temperature sensor, it removes three necessary elements (temperature sensors) from the invention of Shigezawa, and by avoiding heater placement in contact with the blood flow, eliminates the question of biocompatibility and also eliminates the

need acknowledged by Shigezawa for a separate embedded wire to assure continuity of the heater strip.

Claims 1C, D, E, F, and 2C (actually, there is no claim 2C), were rejected over Bakke (6,608,968) in view of Shigezawa (US 6,641,556) and in further view of Jordan (US 5,875,282). The differences with and failure of Shigezawa to teach toward the present invention have been previously discussed.

Bakke (6,608,968) recognized that the captive still air insulation of the patient line of that invention was not adequate for very low flow rates (below 15 ml/min), and claimed to solve the problem using a "clip-on" electrically heated re-usable warming jacket to surround the patient line and to keep it from losing heat to the ambient air. In a very busy operating room, the extra steps involved in retrieving, applying, removing and re-storing the re-usable device are burdensome. Also, the removable external warmer renders the i.v. line less flexible, less drapable and much heavier. The present invention solves the same problem using a low-cost, simple addition to the disposable passively insulated double lumen patient line of Bakke (6,608,968), to wit: deploying a bare flat wire within the still air space to add just enough heat to replace that lost by convection from the outer surface of the tubing. Thus the extra tasks and other drawbacks of the external warming jacket are eliminated.

As applicant is the inventor in both Bakke (6,608,968) and the present invention, has formal training in both heat transfer and medicine (MSME, MD) and has been working actively in the blood warming field for over 20 years,

applicant submits that the present invention is unobvious to one skilled in the art of blood warming considering the references cited.

Jordan Inoperative as Reference on This Invention

The Office Action states, "Jordan discloses a flexible elongated electrical resistance heater segment located within each half of said annular air space,

D.) said heater segments extending in length from about one half to nine tenths the length of said flexible tube flow line, and extending all the way to said outlet end of said flow line,

E.) said internal heater segments being electrically and mechanically joined together at said outlet end of said flow line forming a series electrical resistance heater,

F.) the two proximal ends of said electrical resistance heater being electrically and mechanically adapted to be removably connected to a temperature controller located in said blood warmer apparatus,

G.) said electrical resistance heater being maintained at a controlled temperature of about 42C by a controller mounted inside said blood warmer apparatus,

whereby blood is maintained at normothermic temperature near 42C while passing slowly at very low flow rates through said patient flow line system. ((26) See abstract, detailed description (2))."

Jordan (5,875,282) relates only to a flat plate, dry heat blood warmer and neither relates to nor discloses any matter about i.v. tubing carrying blood or other fluid to the patient. Thus Jordan is an inoperable reference, and does not disclose what is quoted in the O.A. above.

Rejection of Claims 2-7 on Bakke Overcome

The Office Action states, "Bakke discloses the invention substantially as claimed." Regarding the reference Bakke (US 5,420,962), the present invention is entirely different because it uses a small diameter co-extruded patient line and still-air passive insulation augmented by electrical resistance wire heating of the insulating still air. Bakke (5,420,962) attempted to prevent heat loss to ambient air by exposing a regular single lumen i.v. tube to warm air (rather than cool ambient air) by deploying the i.v. line through a large diameter corrugated plastic duct through which warm air was pumped by a fan. Thus, while the present invention and Bakke (5,420,962) address the same problem, i.e. cooling of i.v. fluid in the patient line by ambient air at low flow rates, their approaches are markedly different. Thus Bakke (5,420,962) is inoperable in disclosing or teaching toward the present invention.

Present Invention Is Useful, Novel and Unobvious

The present invention is useful because it allows delivery of normothermic fluid to the patient at very low flow rates, down to essentially zero flow. While the cited reference, Shigezawa, purports to address this problem, his invention is entirely different, much more complicated, probably not practical and has not been commercialized. The only blood warmer available today capable of delivery of low flow normothermic fluid to the patient is the Sims Level 1 "Hotline," which is complicated by needing a water reservoir requiring periodic maintenance, as well as a pump and seals to connect the i.v. line to the warm water system. It circulates warm water through the outer portion of a concentric double lumen tube to warm the blood or other fluid traversing the inner lumen to the patient. The "Hotline" tubing comprises the blood warming heat exchanger, but is limited to relatively low flow rates. The present invention is much simpler and is designed to be employed with a high capacity blood warmer to extend its performance down to essentially zero flow rate.

The present invention is novel in that passive insulation is useful but not fully effective at very low flow rates in the prevention of heat loss to the ambient air resulting in unacceptable cooling of the fluid before it reaches the patient. The present invention efficiently, effectively and simply augments the passive insulation by adding just enough heat to the still air

insulating spaces of the concentric double lumen, low-cost, single-use patient line, assuring the delivery of normothermic fluid to the patient's i.v. site.

Finally, the present invention is unobvious because for many years blood warmers have failed to address the low flow problem, and the when the "Hotline" did so it was with the significant drawbacks of a high maintenance water bath, seals to maintain, and its performance is limited to relatively low flows. Shigezawa purports to solve the problem with a complicated multi-sensor system using a strip or web about 0.1 inch wide and probably about 0.03 inch thick having multiple heating elements, sensors and wires embedded running the entire length of the patient line, immersed in the flowing blood, and employs no insulation from ambient air cooling. This geometry would be very limited in heat transfer capability, even if it could be reduced to practice. To one familiar with the art this seems unlikely. Thus, a long-recognized problem which has eluded solution except by inconvenient means as described above is solved simply and elegantly by the present invention. None of the cited references, singly or in combination, predict or teach toward the present invention, as argued previously.

Conclusion

For all of the above reasons, applicant submits that the specification and claims of this application are now in proper form, and that the claims all define patentably over the prior art. Therefore applicant submits that this application is now in condition for allowance, which action he respectfully solicits.

Conditional Request for Constructional Assistance

Applicant has amended the claims of this application so that they are proper, definite, and define novel structure which is also unobvious. If, for any reason, this application is not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P. paragraphs 2173.02 and 707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible and without the need for further proceedings.

Very respectfully,

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Date: 16 DEC 2005 Applicant:

Allen P. Bakke